UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

October 20, 2005

Docket No. 03037046 License No. 29-31097-01
Control No. 137779

Scott Dennerlein
Radiation Safety Officer
Amicus Therapeutics
6 Cedarbrook Drive
Cranbury, NJ 08512

SUBJECT: AMICUS THERAPEUTICS, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 137779

Dear Mr. Dennerlein:

This is in reference to your letter dated September 14, 2005 applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. Your application should have been signed. Please submit a letter signed by a management representative indicating that management has reviewed the application and concurs in the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in your license.

2. You have requested a quantity of material which requires financial assurance. 10 CFR 30.35 requires that licensees authorized to possess and use unsealed licensed material with a half-life greater than 120 days in quantities greater than those described in 10 CFR 30.35(d) must submit certification for financial assurance or a decommissioning funding plan (DFP) in any new or renewal application. This plan must include an actual estimate of the costs for decommissioning your facility and a mechanism to fund the Plan. The appropriate level of detail for the cost estimate is discussed in Appendix A.3 to Volume 3 of NUREG-1757, “Consolidated NMSS Decommissioning Guidance.” Submit certification for financial assurance in the prescribed amount using one or more of the approved financial assurance mechanisms provided in Chapter 4 to Volume 3 of NUREG-1757. Please follow closely the recommended wording for financial assurance mechanisms found in Appendix A to Volume 3 of NUREG-1757. You may request a license amendment which will limit the possession of unsealed licensed material of half-life greater than 120 days and thereby reduce or eliminate the required financial assurance.

3. You have requested that Scott Dennerlein be named Radiation Safety Officer (RSO) on your license. It appears that this individual may be an outside consultant\contractor. If this is so, in support of this request, please address the following:

a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.

c. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

d. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

4. You have requested that Allan Powe be named as an authorized user and have included his training and experience. Mr. Powe does not appear to have worked with a gamma only isotope such as Iodine 125. In general, authorized users must demonstrate training and experience with the type and quantity of material that they propose to use. In order for Mr. Powe to be considered as an authorized user for the isotope Iodine 125, please include his training and experience with gamma isotopes.

5. It is unclear from the application if you plan to perform iodination procedures. If you plan to perform iodination procedures, then describe your procedures for complying with Sections 20.1203, 20.1204, and 20.1302 of 10 CFR Part 20, for procedures such as protein iodination experiments that may release volatile or gaseous radioactive materials to restricted and unrestricted areas. You should include a description of the type of surveys (e.g., environmental or breathing zone), frequency of surveys, and the individuals who will perform the surveys (e.g., radiation safety officer or investigator), equipment to be used, and the procedures for evaluating the results. If you do not plan on performing iodination experiments then so state.

6. Certain radiation safety training elements appear to be missing from you training outline. These elements are: Survey Program; Waste Procedures; Instrumentation; and Material Receipt. Please add or confirm the following elements are contained in your training program for users of licensed material.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material;** then **toolkit index page.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 137779. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5303.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Thomas K. Thompson

Thomas K. Thompson
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Pedro Huertas, M.D., Chief Development Officer

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SISP Review Complete: DRL
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